IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1797
VISTA HEALTHPLAN, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1833
APOTEX, INC., Plaintiff, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-2768

Goldberg, J. **December 14, 2015**

MEMORANDUM OPINION

This ongoing antitrust case involves four Hatch-Waxman reverse-payment settlement agreements entered into by Cephalon, Inc., the manufacturer of the brand-name pharmaceutical Provigil, and four generic drug companies.[1] Plaintiffs, the Direct Purchasers of Provigil, the End

[1] These companies are: Barr Pharmaceuticals, Inc. ("Barr"); Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"); Teva Pharmaceutical Industries, Ltd. and Teva

Payors of Provigil, and Apotex, a generic competitor, allege that these settlements unlawfully delayed the market entry of generic Provigil in violation of the Sherman Act.

The parties have submitted their pretrial memoranda in anticipation of trial scheduled for February 2, 2016. Presently before me is the "Generic Defendants' Motion to Strike 'Fraudulent Patent' Theory from Plaintiffs' Pretrial Memorandum." Therein, the Generic Defendants assert that Plaintiffs' pretrial memorandum impermissibly includes a theory of per se antitrust liability which stems from the Generic Defendants' alleged knowledge that Cephalon's patent was procured by fraud.

For the reasons explained herein, I conclude that, as it relates to the Generic Defendants, Plaintiffs' per se theory of liability is contrary to the law set out in Federal Trade Commission v. Actavis, Inc., 133 S. Ct. 2223 (2013). Therefore, the Generic Defendants' motion will be granted.[2]

I. FACTUAL AND PROCEDURAL BACKGROUND

The factual and procedural background of this case has been set out numerous times in prior Opinions. Therefore, I will briefly recount only the facts relevant to the instant motion.

In April 1997, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,618,845 ("the '845 patent") to Cephalon, which patented a specific formulation of modafinil known as Provigil, a wakefulness-promoting drug. In 2002, Cephalon was granted a reissue

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Pharmaceuticals USA, Inc. (collectively "Teva"); and Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy") (collectively referred to as the "Generic Defendants").

[2] Because I will grant the Generic Defendants' motion on the basis that Plaintiffs' per se theory is contrary to Actavis, I need not address the Generic Defendants' alternate argument that the Seventh Amendment protects their right to fully litigate any issues relating to materiality in the event that Plaintiffs' knowledge of fraud theory is permitted at trial. (See Defs.' Mot. to Strike, pp. 12-17.)

patent on Provigil, U.S. Patent No. RE 37,516 ("the RE '516 patent"). Cephalon's period of exclusivity for Provigil was scheduled to expire April 6, 2015.

On December 24, 2002, all four Generic Defendants filed Abbreviated New Drug Applications ("ANDAs") for generic Provigil, each certifying under Paragraph IV that Cephalon's patent was either invalid or would not be infringed by their generic Provigil products. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). As first-filers, all of the Generic Defendants were granted 180 days of exclusivity for their generic products, beginning on the first day that they marketed their drug commercially. See id. at § 355(j)(5)(B)(iv). On March 28, 2003, Cephalon sued the Generic Defendants for patent infringement, triggering an automatic thirty-month stay on the approval of their ANDAs (the "Paragraph IV litigation"). See id. at § 355(j)(5)(B)(iii). The Generic Defendants alleged in their answers that the patent was invalid and/or not infringed. During discovery in the Paragraph IV litigation, Mylan, Ranbaxy and Teva amended their answers to also assert that the RE '516 patent was unenforceable due to Cephalon's fraud in the procurement of the patent. Mylan and Ranbaxy moved for summary judgment.

The Paragraph IV litigation between Cephalon and the Generic Defendants was settled between December 2005 and February 2006 while the Generic Defendants' motions for summary judgment were pending. The settlements each permitted the Generic Defendants to launch their generic Provigil products on a "date certain" prior to the expiration of the RE '516 patent—April 6, 2012. The settlement agreements contained provisions for and/or were signed alongside licenses for intellectual property, active pharmaceutical ingredient supply agreements, and pharmaceutical development agreements. Cephalon agreed to pay a total of approximately

$300 million to the Generic Defendants as a result of these agreements.[3] Plaintiffs allege that but for these payments, the Generic Defendants would have launched generic Provigil at risk and the RE '516 patent would have been declared invalid and unenforceable, and thus, lower-cost generic Provigil would have entered the market by June 2006.

This antitrust action was initiated shortly after the settlement agreements were executed. In addition to bringing a number of antitrust claims, Apotex also brought claims for declaratory judgment, seeking to have the RE '516 patent declared unenforceable due to inequitable conduct, invalid and not infringed by Apotex's generic Provigil product. Prior to addressing Plaintiffs' antitrust claims, I held two patent trials to resolve Apotex's patent claims. In the first trial, I found that the RE '516 patent was invalid pursuant to the on-sale bar, and also for derivation, obviousness, and lack of written description. I also held that the patent was unenforceable due to Cephalon's fraud on the PTO because Cephalon had concealed "another company's extensive involvement in the product which is the subject of the claimed invention." See Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011), aff'd, 500 Fed. Appx. 959 (Fed. Cir. 2013) (per curiam).

Plaintiffs have asserted a number of antitrust claims against Cephalon and the Generic Defendants pursuant to the Sherman Act and state law. After various settlements and following my rulings on the parties' numerous motions for summary judgment, Plaintiffs' remaining claims are as follows: (1) the Direct Purchasers' claims against Mylan and Ranbaxy that the reverse-payment settlement agreements constituted illegal agreements in restraint of trade under section 1 of the Sherman Act; (2) the End Payors' claims against Ranbaxy, Teva, Barr and

[3] Additional details regarding these settlement agreements and the Hatch-Waxman administrative framework may be found at this Court's memorandum opinion addressing Defendants' motions for summary judgment on Plaintiffs' Actavis claims. See King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402 (E.D. Pa. 2015).

Cephalon that the reverse-payment settlement agreements constituted illegal agreements in restraint of trade, and a Walker Process monopolization claim brought against Cephalon only, all of which are brought under various states' antitrust, consumer protection and unjust enrichment laws; and (3) Apotex's claims against Cephalon for Walker Process fraud and sham litigation in violation of Section 2 of the Sherman Act, a claim for tortious interference with prospective business relations against Cephalon, and claims against all Defendants for violations of Sections 1 and 2 of the Sherman Act arising out of the reverse-payment settlement agreements.

Plaintiffs' pretrial memorandum describes their theories of liability relating to the allegedly anticompetitive settlement agreements. Therein, Plaintiffs articulate a liability theory pursuant to Actavis that the settlement agreements are unlawful under the rule of reason because Cephalon made large and unexplained payments to the Generic Defendants. In addition, Plaintiffs' pretrial memorandum also includes the following per se theory of liability:

> [E]ach of the Generic Defendants believed at the time they agreed to delay competition with Cephalon that the '516 patent had been obtained by fraud and was invalid and unenforceable. Consequently, even though they knew that there was no enforceable patent that would prevent them from coming to market, each Generic Defendant agreed not to compete with Cephalon for over six years. Absent a patent these agreements not to compete constitute per se illegal market allocation agreements. Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990). . . .
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> As a leading antitrust treatise has commented, "some patent infringement cases are so weak that they are worthy of condemnation even aside from any pay-for-delay considerations. Anticompetitive provisions in a settlement agreement on an obviously invalid patent, or where the patent is clearly not infringed, are unlawful in any market and whether or not a payment for delay has occurred." . . . 12 Philip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶2406 (4th ed. 2015).

(Pls.' Pretrial Mem., p. 20 n.11.)

The Generic Defendants assert that this theory should be stricken from Plaintiffs' pretrial memorandum because: (1) Plaintiffs' per se fraud theory of liability is contrary to the law; and

(2) this Court has previously ruled that no Walker Process fraud claim has been or could be asserted against the Generic Defendants.[4] All Plaintiffs respond that scope of the patent case law predating Actavis, which recognized that settlements involving fraudulent patents were stripped of antitrust immunity, applies to their Section 1 claims against the Generic Defendants. Further, they assert that, without an enforceable patent as a defense, the settlement agreements constitute naked market allocation agreements subject to per se treatment, as described in Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990). Plaintiffs also argue a Walker Process fraud theory may be asserted against the Generic Defendants, despite the fact that they were not the original patentees.

Apotex also raises a procedural issue, contending that a motion to strike is an inappropriate avenue to raise this challenge. Apotex urges that the Generic Defendants' motion is "really a renewed motion for summary judgment on liability." (Apotex's Resp., p. 2.) Before considering the substantive legal issues, I will first address Apotex's procedural objection.

II. APOTEX'S PROCEDURAL CHALLENGE

Apotex cites to Rule 12(f) of the Federal Rules of Civil Procedure, which governs motions to strike matters from pleadings, and notes that a pretrial memorandum is not a pleading. To the extent that I choose to consider the Generic Defendants' challenge to Plaintiffs' per se

[4] The Generic Defendants also assert that Plaintiffs did not timely plead or disclose this theory of liability. However, upon review of Plaintiffs' complaints, as well as numerous briefs filed in connection with the parties' motions for summary judgment, it is clear that this theory of liability has been raised and briefed by the parties throughout the course of this litigation. (See DPCP 2d Am. Compl. ¶¶ 72-82; Rite Aid Compl. ¶¶ 68-70; Walgreens Am. Compl. ¶¶ 71-73; EP Am. Compl. ¶¶ 71-83; Apotex 2d Am. Compl. ¶¶ 68-73, 87; Apotex's Mem. In Supp. of Partial Summ. J. of Antitrust Liability, pp. 4, 10, 23; Apotex's Comb. Mem. In Opp. to Defs.' Mot. for Summ. J. on Settlement Agreements, pp. 14-15; DPCP's Reply Mem. In Supp. of Mot. to Preclude, p. 5 n.1; DPCP Mem. In Opp. to Defs.' Mot. for Summ. J. on Settlement Agreements, pp. 2-3.) Therefore, I do not agree with the Generic Defendants' argument that they were not put on notice of Plaintiffs' per se theory of liability.

theory of liability based on knowledge of fraud, Apotex "seek[s] additional leave to detail the evidence supporting its claim." (Id. at p. 9.)

Apotex's request to detail evidence supporting its per se claims is unnecessary. I am well-versed in Plaintiffs' evidence allegedly establishing the Generic Defendants' knowledge of fraud. This evidence was carefully detailed in Plaintiffs' Combined Statement of Uncontested Material Facts filed in connection with the parties' motions for summary judgment. Indeed, Plaintiffs' responses to the instant motion cite extensively to Plaintiffs' Combined Statement of Uncontested Material Facts, as well as to Plaintiffs' briefing filed in connection with two motions for summary judgment, which I have thoroughly reviewed. In considering the legal merits of Plaintiffs' per se theory of liability against the Generic Defendants, I will consider these facts in the light most favorable to Plaintiffs.

Apotex acknowledges in its briefing that the Generic Defendants are "essentially moving (albeit prematurely) to establish the legal standard that will underlie the jury instructions for [Plaintiffs'] fraudulent patent theories." (Apotex's Resp., p. 8.) This is an accurate description of the motion, and I will construe it as such. Apotex is correct in noting that a ruling from this Court on Plaintiffs' per se theory of liability will shape the issues to be presented to the jury. Whether the Generic Defendants may be held per se liable for entering into the settlement agreements regardless of any large and unjustified payment is an important legal issue that I have yet to rule on in the course of this litigation.[5] Thus, although resolution of this issue may not have been presented in the best procedural fashion, it needs to be resolved.

[5] Plaintiffs' per se theory of liability was briefed at the time of summary judgment. In my Opinion denying Defendants' motions for summary judgment on the antitrust challenges to the settlement agreements, I characterized Plaintiffs' knowledge of fraud argument as follows:

> The private Plaintiffs argue that even if they do not satisfy their burden under Actavis, summary judgment may not be granted on their challenges to the

For the reasons that follow, I find that Plaintiffs' claims against the Generic Defendants must be proven under the Actavis rule of reason, and that a per se theory of liability against the Generic Defendants is not legally viable. Therefore, I will grant the Generic Defendants' motion and preclude Plaintiffs from arguing this per se theory of liability before the jury.

III. LEGAL ANALYSIS

The legal framework governing reverse-payment settlement antitrust actions has changed significantly since these consolidated cases were first filed in 2006. In the early stages of this case, when deciding the parties' motions to dismiss, I concluded that the scope of the patent test should apply to Plaintiffs' antitrust claims challenging the settlement agreements. King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F. Supp. 2d 514, 524-29 (E.D. Pa. 2010). However, three years later, the United States Supreme Court announced in Actavis that reverse-payment settlement agreements should be analyzed under the antitrust rule of reason. Acknowledging that Actavis significantly changed the standard to be applied in reverse-payment settlement cases, I applied the rule of reason in denying Defendants' motions for summary judgment arising out of the settlement agreements. See King Drug Co. of Florence, Inc., 88 F. Supp. 3d 402.

In advancing their per se "knowledge of fraud" claims against the Generic Defendants, Plaintiffs first assert that Actavis did not involve a patent procured by fraud. Thus, according to Plaintiffs, the scope of the patent case law, which recognized a lack of immunity for settlements

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> settlement agreements due to their allegations of fraud in the procurement of Cephalon's patent. They assert that proof of Walker Process fraud renders the settlement agreements per se violations of the Sherman Act, and thus, evidence of fraud is sufficient to deny summary judgment. The Generic Defendants respond that they may not be held liable under the antitrust laws for Cephalon's fraud.

King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402, 414 n.12 (E.D. Pa. 2015). At that time, I declined to resolve whether knowledge of fraud could be used to hold the Generic Defendants per se liable because Plaintiffs had presented sufficient evidence to survive summary judgment under the Actavis framework. Id.

involving fraudulent patents, should apply to their claims against the Generic Defendants. Second, with respect to Apotex's conspiracy to monopolize claims under Section 2 of the Sherman Act, Apotex argues that, as Cephalon's co-conspirators, the Generic Defendants may be held liable under a Walker Process theory of liability. I will address each of these arguments in turn.

A. Does Actavis Permit the Generic Defendants to Be Held Per Se Liable in a Reverse-Payment Settlement Case Where the Generic Defendants Learned of Facts Indicating that the Patent Was Fraudulently Obtained?

In order to properly understand and address Plaintiffs' first argument, that per se treatment is appropriate under pre-Actavis scope of the patent case law, a brief recitation of the relevant precedent is necessary.

1. The Scope of the Patent Test

Before the Supreme Court announced in Actavis that antitrust challenges to reverse-payment settlement agreements should be reviewed under the rule of reason, the majority of courts applied the scope of the patent test. That framework attempted to strike a balance between the right to exclude that is granted to a patent holder and the interests of competition, providing antitrust immunity where the alleged restraint on trade fell within the exclusionary scope of the patent. Where an agreement exceeded the exclusionary potential of the patent, the court could consider the anticompetitive effects that arose as a result. King Drug Co. of Florence, Inc., 702 F. Supp. 2d at 526 (quoting Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1305-06 (11th Cir. 2003)).

However, courts applying this test found that even if the reverse-payment settlement fell within the scope of the patent—i.e., the settlement agreement provided for generic entry prior to the patent's expiration—evidence of fraud or sham litigation would nonetheless allow an

antitrust claim to move forward. See, e.g., Federal Trade Commission v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012) ("absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent"). I affirmed this principle in my motion to dismiss Opinion, stating that "several Plaintiffs have asserted that Cephalon misrepresented material facts regarding its clinical trials to the PTO and that the Generic Defendants were aware of these facts when they entered into the settlement agreements with Cephalon. Applying the scope of the patent framework allows exploration of these allegations." King Drug Co. of Florence, Inc., 702 F. Supp. 2d at 529 (internal citations omitted).

Plaintiffs rely upon these scope of the patent cases to support their theory that per se antitrust liability can be established if the Generic Defendants settled the Paragraph IV litigation with the knowledge that Cephalon's patent was procured by fraud. Plaintiffs assert that without the immunity otherwise provided by a patent, the reverse-payment settlements between Cephalon and the Generic Defendants are garden variety restraints of trade without redeeming value, subject to per se treatment. However, Plaintiffs' theory fails to recognize that the legal landscape changed dramatically in the wake of Actavis.

2. Federal Trade Commission v. Actavis, Inc.

In 2013, the United States Supreme Court considered the appropriate standard to apply to antitrust challenges to reverse-payment settlement agreements. Actavis, 133 S. Ct. 2223. The Court first noted that exceptions to patent-related antitrust immunity had been recognized in certain situations—for example, where a patent holder procured its patent by fraud and enforced it to keep competitors off of the market. Id. at 2231 (citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965)). After determining that the scope of the patent

need not end the inquiry, the Court found that reverse-payment settlements should be analyzed under the antitrust rule of reason. Id. at 2234-37. In so holding, the Supreme Court explicitly rejected the application of the scope of the patent framework, as well as quick-look and per se liability, in analyzing an antitrust claim challenging a reverse-payment settlement. Id. at 2234, 2237.

The Court further indicated that in order for a plaintiff to meet its initial burden under the rule of reason, it was required to demonstrate anticompetitive effects, including evidence of a large reverse payment. See King Drug Co. of Florence, Inc., 88 F. Supp. 3d at 415 (interpreting the rule of reason framework under Actavis). The burden then shifts to the defendant to provide procompetitive justifications, such as evidence that the payment constitutes avoided litigation costs or fair value for services. Id. at 415-16. The plaintiffs can then rebut the defendant's justifications. Id. at 416. Ultimately,

> the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. . . . These complexities l[ed] [the Court] to conclude that the [plaintiff] must prove its case as in other rule-of-reason cases.

Actavis, 133 S. Ct. at 2237. In response to criticisms that potential antitrust scrutiny would prevent settlements, the Court indicated that the parties may settle in other ways without risking antitrust scrutiny—"[f]or example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." Id.

3. What is the Appropriate Standard to Be Applied to Plaintiffs' Section 1 Claims Against the Generic Defendants?

With this background in mind, I next consider whether settlement of Hatch-Waxman Paragraph IV litigation can result in per se antitrust liability where the settling Generic Defendants allegedly acquired knowledge indicating that the patent was procured by fraud, irrespective of whether they received a large and unjustified payment.[6] For the reasons that follow, I disagree with Plaintiffs and find that the Actavis rule of reason controls Plaintiffs' claims against the Generic Defendants.

While Plaintiffs attempt to garner support for their theory from the previously-described case law interpreting the scope of the patent framework, the Supreme Court has definitively held that this framework does not apply in reverse-payment settlement cases. Actavis, 133 S. Ct. at 2231. While I recognize that Actavis did not involve allegations of a fraudulently-procured patent, neither did it provide an exception to the rule of reason analysis for settlements where the Generic Defendants had raised allegations of fraud or sham in the Paragraph IV litigation. The Supreme Court certainly had the opportunity to do so, as it considered a number of scope of the patent cases cited by Plaintiffs, and determined that a rule of reason analysis was more appropriate. See Actavis, 133 S. Ct. at 2230 (reviewing the scope of the patent framework applied by the Eleventh Circuit in Valley Drug Co., 344 F.3d at 1304, which recognized an exception for fraud and sham litigation). The Court also extensively considered, and rejected, the position that reverse-payment settlements were presumptively unlawful. Id. at 2237 ("The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful . . . We decline to do so.")

[6] At the time of the reverse-payment settlements, no final judgment regarding the fraud allegations had been reached in the Paragraph IV litigation. I take no position as to the appropriate legal standard for a case where parties to Hatch-Waxman Paragraph IV litigation settle after a judicial determination of fraud has been entered.

Plaintiffs' argument for per se antitrust liability against Generic Defendants that settle Hatch-Waxman litigation involving an allegedly fraudulent patent, without any consideration of whether a large and unjustified payment was made, is very similar to the position rejected by the Honorable Harvey Bartle, III of this Court in Federal Trade Commission v. AbbVie, Inc., 2015 WL 2114380 (E.D. Pa. May 6, 2015).

In AbbVie, the FTC sued the brand-name manufacturer of Androgel, a testosterone drug, as well as the manufacturer of an allegedly non-infringing generic product, for entering into an agreement in restraint of trade under section 1. Id. at *1. The FTC alleged that the brand initiated sham patent infringement litigation against the generic for the purpose of delaying generic entry. Id. The generic had also filed an antitrust counterclaim during the Paragraph IV litigation, asserting "that the litigation against it was a sham intended merely to extend the plaintiffs' Androgel monopoly with the mandatory 30-month stay." Id. at *4. The generic moved for summary judgment on its sham litigation counterclaim during the Paragraph IV litigation. Id. The parties settled in 2011, with the brand agreeing to permit the generic to market a generic testosterone gel in 2014, nearly six years prior to the patent's expiration. Id. The brand also agreed to grant the generic a license for a popular cholesterol drug, which the FTC characterized as a reverse payment. Pointing to the counterclaim and motion for summary judgment to demonstrate the generic's knowledge that the litigation was a sham, the FTC argued that the settlement constituted an illegal restraint of trade on the part of both the brand and the generic. Id. at *8.

Judge Bartle rejected the FTC's argument for several reasons. First, he found that the license for the popular cholesterol drug did not constitute a reverse payment. Id. at *7. He next considered whether allegations that the generic knew that the infringement litigation was a sham

could sustain an antitrust claim absent evidence of a reverse payment. Id. at *8. Judge Bartle determined that the FTC's allegations were insufficient and granted the defendants' motion to dismiss, finding that "there is no allegation in the complaint that [the generic] conspired with the [brand] to bring a frivolous patent action against it for some anticompetitive purpose." Id. Instead, the generic was defending itself against what it perceived to be sham litigation. Id. "No judicial determination of the sham issue had been made when the parties settled the case," and therefore "[t]he FTC's allegations that the court would likely rule in favor of [the generic] is merely speculation." Id. Judge Bartle remarked:

> If we were to accept the validity of the FTC's line of reasoning, it would mean that a party in [the generic's] position would risk antitrust liability by claiming the underlying action brought against it is baseless and thereafter agreeing to settle. The only way for the claimed infringer to avoid the risk would be not to raise the issue of sham litigation or to litigate the action fully with all the attendant expense and use of judicial resources. Such a result would undermine the salutary public policy favoring settlements far beyond the holding of Actavis.

Id.

I agree with Judge Bartle's analysis in AbbVie, and find that it applies to the case before me. Plaintiffs' per se theory of liability based on the Generic Defendants' knowledge of fraud relies on the Generic Defendants' court filings in the Paragraph IV litigation and my ruling several years later that the RE '516 patent is invalid and was procured by fraud. Prior to a judgment conclusively establishing that Cephalon obtained the RE '516 patent through fraud on the PTO, the Generic Defendants' answers alleging invalidity and fraud in the Paragraph IV litigation were simply allegations. The fact that, several years later, I agreed with those allegations does not change this fact.

As Judge Bartle aptly concluded, adopting Plaintiffs' reasoning would create a Hobson's choice[7] for generic pharmaceutical companies. A generic that files a Paragraph IV certification—a procompetitive act that the Hatch-Waxman Act seeks to encourage—and subsequently becomes a defendant in Paragraph IV litigation, may face what has the potential to be either sham litigation or the brand's enforcement of a fraudulent patent. The generic cannot know for sure until the action is litigated to conclusion. To accept Plaintiffs' theory would require the generic to choose between: (1) declining to raise these potential defenses for fear that, if the parties eventually settle, those defenses would later be used to establish a per se violation of the antitrust laws; or (2) raise the defenses and litigate the case to conclusion without considering settlement. Such a result would significantly undermine the public policies encouraging patent challenges, as well as settlement.

Tellingly, in AbbVie, the FTC acknowledged at oral argument that if the Court found that the cholesterol drug license did not constitute a reverse payment—which the Court did indeed find—the generic would not be exposed to antitrust liability, even if it had entered into the settlement agreement with knowledge that the infringement litigation might be a sham. Id. at *9. This is because the Actavis Court specifically endorsed Hatch-Waxman settlements that allow the generic to enter the market prior to the expiration of the patent, so long as no reverse payment is made. Actavis, 133 S. Ct. at 2237 (generic and brand may settle in other ways, such as "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point"). And yet, liability for this type of settlement is exactly what Plaintiffs request. Plaintiffs seek to hold the Generic Defendants per se liable for a Paragraph IV settlement agreement that allowed them to

[7] A Hobson's choice is "the necessity of accepting one of two or more equally objectionable alternatives." *Hobson's Choice Definition*, MERRIAM-WEBSTER.COM, http://www.merriam-webster.com/dictionary/hobson's%20choice (last visited Oct. 14, 2015).

enter the market prior to the expiration of the patent, regardless of any reverse payment, simply because the Generic Defendants had previously raised an unconfirmed allegation of fraud.

In Actavis, the Supreme Court balanced numerous conflicting public policies in deciding that a rule of reason analysis that includes considerations of whether the reverse payment was large and unexplained is the appropriate standard of review for antitrust challenges to reverse-payment settlements. These "complexities" are simply not accounted for in cases condemning naked market allocation agreements as per se unlawful, such as Palmer, a case cited in Plaintiffs' pretrial memorandum. The defendants in Palmer were competitors that had entered into a licensing agreement dividing the market for bar review courses between them geographically. 498 U.S. at 47. The Supreme Court held that this horizontal agreement constituted a per se violation of section 1 of the Sherman Act because it was a "naked restraint[ ] of trade with no purpose except stifling of competition." Id. at 49 (quoting United States v. Topco Assoc., Inc., 405 U.S. 596, 608 (1972)). Palmer did not include unconfirmed allegations that a patent was fraudulent or invalid, nor was the agreement in that case the product of a settlement, let alone a Hatch-Waxman reverse-payment settlement. The "complexities" that are involved in reverse-payment settlement cases, the inherent tension between patent law and antitrust law, as well as the public policy favoring settlement, led the Supreme Court in Actavis to conclude that a rule of reason analysis, as opposed to a quick-look or per se approach, was appropriate.[8] Actavis, 133 S. Ct. at 2237. Therefore, I am not convinced by Plaintiffs' argument that Palmer, as opposed to

[8] While Plaintiffs cite to certain statements in United States v. Singer Mfg. Co., 374 U.S. 174 (1963) in support of their per se theory of liability, those statements are derived from Justice White's concurrence and were not adopted by the Singer majority. Therefore, I do not find this argument convincing.

Actavis, should control the antitrust framework for Plaintiffs' allegations against the Generic Defendants.[9]

4. Can Per Se Liability Be Established as to the Generic Defendants Through Apotex's Section 2 Conspiracy Claims under Walker Process?

As to Apotex's claims for conspiracy to monopolize in violation of Section 2 of the Sherman Act, Plaintiffs argue that if they can demonstrate that Cephalon committed Walker Process fraud, the Generic Defendants, as co-conspirators in enforcing the patent, can be held liable on a per se basis. I disagree.

First, I note that I previously held that a Walker Process fraud claim has not and could not have been brought against the Generic Defendants. "[T]he Generic Defendants are not parties to the Walker Process claims, because they neither procured nor enforced the patent." King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2014 WL 982848, at *13 (E.D. Pa. Mar. 13, 2014); see also Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998) (patentee who brings a patent infringement suit may be subject to antitrust liability where patent was procured by fraud).

Despite my prior ruling, Plaintiffs point to cases where a court has determined that parties other than the original patentee may be subject to a Walker Process theory of liability. See Ritz Camera & Image, LLC v. Sandisk Corp., 700 F.3d 503, 506 (Fed. Cir. 2012) (noting that a patent assignee may be subject to Walker Process if it "maintained and enforced the patent with knowledge of the fraudulent manner in which it was obtained"); Nobelpharma, 141 F.3d at 1068-

[9] This issue regarding a per se theory of liability based on the Generic Defendants' knowledge of Cephalon's fraud has also arisen in the context of the Direct Purchasers' motion to amend my class certification Order and for approval of the form and manner of notice to the Direct Purchaser Class. (See Dkt. No. 06-1797, Doc. No. 844.) For all of the reasons recited herein, including allegations of the Generic Defendants' knowledge of fraud in the class notice would be equally inappropriate.

70 (exclusive licensee that was involved in the procurement of patent and enforced said patent in three separate lawsuits may be deprived of immunity under Walker Process). Plaintiffs argue that "[s]uch liability should also extend to non-exclusive licensees who conspire with the patentee to enforce the [ ] patent . . . [j]ust as this court found Cephalon responsible for the fraud of its employees under 'basic principles of agency law.'"[10] (Apotex's Resp., p. 14.)

As noted above, I have already held that a Walker Process monopolization claim cannot be maintained against the Generic Defendants. Plaintiffs' continued conspiracy arguments do not change that conclusion. It is undisputed that the Generic Defendants had no involvement in the procurement of the patent, nor did they somehow conspire to enforce the patent by initiating the infringement lawsuit. Instead, they settled a lawsuit where they may have had knowledge of facts indicating fraud may have occurred. But, at the time the settlements at issue were reached, that knowledge had not yet been confirmed by a judgment. For all of the reasons recited above, I find that Actavis' rule of reason analysis is the appropriate framework for Apotex's section 2 claims against the Generic Defendants.

As I find that neither of Plaintiffs' per se theories of liability against the Generic Defendants are cognizable, the Generic Defendants' motion will be granted, and Plaintiffs shall refrain from arguing such legal theories at trial.

[10] To support their argument, Plaintiffs refer to my ruling in Federal Trade Commission v. Cephalon, Inc., No. 08-2141, a case consolidated in the In re Modafinil Antitrust Litigation that has settled. In resolving the FTC's motion for partial summary judgment based on my findings in the patent trial, I determined that "basic principles of agency law, which holds that a corporation is charged with the knowledge of acts done by its agents acting within the scope of their employment" prevented Cephalon from asserting that it did not know that the patent was fraudulent at the time of the reverse-payment settlements. Federal Trade Commission v. Cephalon, Inc., 36 F. Supp. 3d 527, 535-36 (E.D. Pa. 2014). As the Generic Defendants were not employees of Cephalon, nor were they in any way involved in the procurement of the RE '516 patent, my holding in FTC is of limited relevance here.

B. Are Plaintiffs' "Knowledge of Fraud" Allegations Relevant to the Actavis Rule of Reason Analysis?

Finally, Plaintiffs argue that facts indicating that the Generic Defendants knew of Cephalon's fraud "are also relevant to [Plaintiffs'] Actavis reverse payment case because they speak to the parties' beliefs about the strength of the patent and its ability to inhibit competition." (Apotex's Resp., p. 9.) Here, I agree with Plaintiffs.

When deciding the motions for summary judgment predicated on my rulings in the patent trials, I touched on this issue, holding that even though the Walker Process claims did not apply to the Generic Defendants,

> [t]he Generic Defendants will still be able to argue, should they so choose, that settlement was pro-competitive, and that they were unaware of Cephalon's fraud or the invalidity of the patent. In short, nothing in this opinion should be interpreted to limit the ability of the Generic Defendants to put on their defense.

Id. at *13.[11] By acknowledging that the Generic Defendants' defense may include evidence that they were unaware of Cephalon's fraud or the patent's invalidity, this passage implicitly recognizes that the Generic Defendants' knowledge of fraud and invalidity are potentially relevant to Plaintiffs' Actavis claims.

[11] The Direct Purchasers have insisted on numerous occasions that I did not conclusively decide in the collateral estoppel Opinion whether partial summary judgment should be entered against Cephalon and the Generic Defendants on the invalidity of the RE '516 patent and Walker Process materiality. (See, e.g., DP Resp., pp. 17-18.) While I believe my rulings are clear, in deference to counsel for the Direct Purchasers, I will attempt to clarify.

Partial summary judgment has been granted in favor of Plaintiffs against Cephalon as to Walker Process materiality. King Drug Co. of Florence, Inc., 2014 WL 982848, at *12 (finding that collateral estoppel applies to invalidity rulings of derivation, obviousness and on-sale bar and that Walker Process materiality is established as to Cephalon). However, because a Walker Process claim had not been pled as to the Generic Defendants (nor was there any evidence to support a finding of Walker Process fraud as to these Defendants), collateral estoppel as to invalidity did not conclusively establish any element of any claim brought against the Generics. Id. at *13 ("validity is not identical to any of the claims brought against [Generic Defendants]," so "the fact that the patent was found invalid in the 2011 Apotex patent litigation should have no bearing on the proofs necessary to hold the Generic Defendants liable for antitrust violations"). Therefore, summary judgment was denied as to the Generic Defendants. Id.

I further explored the relevance of this evidence in resolving Defendants' motions for summary judgment on Plaintiffs' claims arising out of the settlement agreements. In considering the evidence that Plaintiffs had presented under the Actavis rule of reason to rebut Defendants' asserted procompetitive justifications, I noted that "the arguments raised by the Generic Defendants in the Paragraph IV litigation largely mirrored the facts that were eventually used to invalidate and render unenforceable the RE '516 patent, demonstrating the Generic Defendants' knowledge of those facts." King Drug Co. of Florence, Inc., 88 F. Supp. 3d at 419.

Actavis states that an unreasonable restraint of trade occurs when the patent-holder makes a large and unexplained payment to a generic challenger in Paragraph IV litigation, where the "payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." Actavis, 133 S. Ct. at 2236. "[T]he relevant antitrust question is: What are [the] reasons" for the defendants entering into a settlement agreement with a reverse payment? Id. at 2237. If it was to avoid patent invalidity, noninfringement, or a finding of inequitable conduct, and "share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." Id. Cephalon and the Generic Defendants' knowledge of the strength and/or weakness of the patent is thus relevant to this determination.

Indeed, the Generic Defendants seem to acknowledge the relevance of this evidence, indicating that Plaintiffs may "present evidence that the Generic Defendants' conduct was unreasonable under the Actavis Rule of Reason framework because Cephalon's patent was 'weak' or 'unenforceable.'" (Defs.' Mot. to Strike, p. 12 n.3 (emphasis in original).) I agree, and find that while a per se theory of liability is contrary to the law, evidence that the Generic

Defendants knew of the RE '516 patent's weakness may be introduced at trial in support of Plaintiffs' claims under the rule of reason.

IV. CONCLUSION

For the above-stated reasons, I conclude that a per se theory of liability stemming from the Generic Defendants settling the Paragraph IV litigation despite being aware of facts indicating that the RE '516 patent had been procured by fraud is contrary to the law and will not be permitted at trial. The Generic Defendants' alleged knowledge of the weaknesses of Cephalon's patent is admissible evidence to be considered in the rule of reason analysis. The parties shall limit their pretrial submissions and arguments at trial accordingly.

An appropriate Order follows.